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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,805	10/03/2003	Madhavi Krishnan	UM-07718	3256

7590

12/06/2006

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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/678,805	<b>Applicant(s)</b> KRISHNAN ET AL.	
	<b>Examiner</b> Cynthia B. Wilder, Ph.D.	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/2/2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 22-25 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-25 and 27-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/2/2006 has been entered. Claims 1-21 and 26 have been canceled. Claims 22-25 and 27-31 are pending in the instant invention and addressed below.

### ***Previous Rejection***

2. The claim rejection under 35 USC 112 second paragraph is withdrawn in view of Applicant's cancellation of the claims. The prior art rejection under 35 USC 102(e) and 35 USC 103(a) is withdrawn in view of Applicant's cancellation of the claims. The indication of allowability of the claims 22-25 and 27-31 is withdrawn in view of the new grounds of rejection below.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 22, 25 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Ecke et al (International Journal of Engineering Science, vol. 36, pages 1471-1480, 1998) in view of Vorobieff et al (Physica D, vol. 123, pages 153-160, 1998), and further in view of Selvaganapathy et al (Proceedings of the IEEE, vol. 91, no. 6, June 2003). Regarding claims 22, 25, and 27, Ecke et al teach a reaction vessel and method, as disclosed by Vorobieff et al (page 154-155, section entitled "experimental setup and data acquisition system), said reaction vessel comprising a top and a bottom, a heat source, contacting said bottom of said reaction vessel and an active cooling means contacting said top of said reaction vessel, wherein said cooling means is selected as a cooling bath and a refrigeration device; and a solution; introducing said solution into said vessel and creating at least one convection cell by applying heat to said bottom of said vessel with said heat source and cooling said top of said vessel with said cooling means under appropriate conditions (page 1473, section entitled "2 Experiment"). Ecke et al further teach wherein the reaction vessel is configured with an aspect ratio of 5<sup>1</sup> (see abstract and page 1473, third paragraph where Ecke et al discuss a radius-to-height ratio of 1, 2.5 or 5).

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<sup>1</sup> The limitation "at least 3.3" broadly encompasses an aspect ratio of 3.3 or higher.

Ecke et al in view of Vorobieff do not teach wherein the solution introduced into the reaction vessel comprises a plurality of reactants, wherein said reactants comprise nucleic acid comprising and primers substantially homologous to at least a portion of said target.

Selvaganapathy et al provides a review article on the recent progress in microfluidic devices for nucleic acid assays, including PCR microdevices for use in amplification of nucleic acid molecules. Selvaganapathy et al teach that the use of naturally developed Raleigh-Benard convection between two regions of differing temperature may be used for performing PCR (page 955, second column, bottom of first full paragraph). Selvaganapathy teach that the amplification reaction will comprises the use of reactants such a nucleic acid comprising a target and primer substantially homologu to a least a portion of said target. Additionally, Selvaganapathy et al teach wherein the amplified products are formed (page 954-955, section entitled "Amplification Chips").

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention that a solution comprising a plurality of reactants, such as nucleic acid targets and primers, can be applied to the reaction vessel and method as taught by Ecke et al in view of Vorobieff et al with a reasonable expectation of success based on the teachings of Selvaganapathy et al that the use of naturally developed Raleigh-Benard convection between two regions of differing temperature may be used for performing PCR amplification procedures.

Regarding claim 28, Ecke et al teach wherein the reaction vessel comprises material comprising PLEXIGLASS and silicones (page 1473, section entitled "Experiment").

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 22-25 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sogard (2003/0077599, October 23, 2001) in view of Tomishima et al (5, 169,918, September 8, 1992). Regarding claim 22, Sogard teaches a method, comprising providing a reaction vessel comprising a top and a bottom, a heat source contacting said bottom of said reaction vessel, an active cooling means contacting said top of said reaction vessel, wherein said cooling means comprises a water bath and solution comprising a plurality of reactants; introducing said solution into said reaction vessel; and creating a convection cell by applying heat to said bottom of said vessel with said heat source and cooling said top of said vessel with said cooling means under such conditions that said reactants form a reaction product (Figure 1; Figure 3; 0013-0014; 0040-0045, 0047; and 0049-0052).

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Sogard does not teach wherein the reaction vessel is configured with an aspect ratio of at least 3.3.

Tomishima et al teach an apparatus or reaction vessel comprising a top and bottom, a heat source contacting the bottom and active cooling means contacting the top, wherein the reaction vessel is configured with an aspect ratio of 4 or more (col. 5, lines 43-47; col. 6, lines 13-23, 60-68; col. 7, lines 20-25, 34-40). Tomishima et al teach that an apparatus configured with an aspect ratio of 4 or more with a temperature control system allows for a wide distribution of polymerization degrees and uniform temperature distribution (col. 6, line 61 to 68; col. 7, lines 18-25, 34-36).

It would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have been motivated to modify the apparatus of Sogard to encompass an aspect ratio of at least 3.3 for the benefit of obtaining a uniform temperature distribution between the upward and downward directions of the reaction vessel as taught by Tomishima et al.

Regarding claim 23, Tomishima et al teach wherein a cross section of the reaction vessel may have elements that are rectangular or circular or elliptic or other similar forms (col. 7, lines 65-67).

Regarding claim 24, Sogard teaches the reaction vessel of claim 22, wherein the reaction vessel is with corners (see figure 1 and 2).

Regarding claims 25 and 27, Sogard teaches the method of claims 22 as previously described above. Sogard et al teach that the method and device can be used in hybridization and binding assays and may comprise amplified nucleic acids, via PCR techniques (0056-0057). Therefore, a nucleic acid comprising a target and primer substantially homologous to a least a

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portion of said target are inherent in the teaching of the nucleic acid amplification reaction via PCR.

Regarding claim 28, Sogard teaches the method of claim 22, wherein said reaction vessel comprises at least functionalized glass (0065, Figure 1).

Regarding claim 29, Sogard teaches the method of claim 22, wherein said reaction vessel is part of an array (0065, Figure 1).

Regarding claim 30, Sogard teaches the method of claim 22, wherein a temperature gradient of between about 5 degrees Celsius and 25 degrees Celsius or more preferably about 10 degrees Celsius/mm is used (0047).

Regarding claim 31, Sogard teaches the method of claim 22, also providing an input tube connected to a inlet port or fluidic interface port, which is in fluid communication with said reaction vessel (0053 and Figure 1).

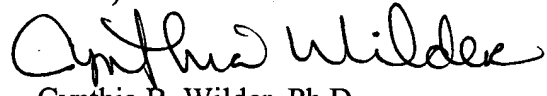
### ***Conclusion***

9. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cynthia B. Wilder, Ph.D.

Patent Examiner

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( 11/29/2006